

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS**

IN RE: TESTOSTERONE REPLACEMENT
THERAPY PRODUCTS LIABILITY
LITIGATION

Case No. 1:14-cv-1748
MDL No. 2545

Hon. Matthew F. Kennelly

THIS DOCUMENT RELATES TO ALL
CASES

**PLAINTIFFS' STEERING COMMITTEES' SUPPLEMENTAL SUBMISSION IN
SUPPORT OF ITS PROPOSED UNIFIED CASE MANAGEMENT PLAN**

I. Introduction

As the Court's October 31, 2014 Minute Entry pointed out (Dkt. No. 451), the Plaintiffs' Steering Committee ("PSC") was both unaware and surprised to learn that the AbbVie Defendants' amended Unified Case Management Plan would include a request for a modified version of bifurcated general causation.¹ This concept is one that the PSC believed that the Court had already largely rejected by suggesting that no efficiencies were gained by any such bifurcation. As such, and for the reasons set forth below, the Court should reject the AbbVie Defendants' second bite at the same apple, which tries to force this Court to reconsider the guidance it previously provided to the parties relating to bifurcation of general causation discovery.

As set forth below, this proposed modified bifurcation: (a) greatly and insurmountably prejudices the Plaintiffs and will cause significant delays and inefficiencies as well as being wholly inconsistent with most multidistrict litigation ("MDL") practices in pharmaceutical cases; (b) has no valid basis for being adopted by this Court under the circumstances presented here; (c) as

¹ Under this modified version of bifurcated general causation, initial expert discovery, including expert reports, depositions and/or motions would be limited to the issue of general causation, and the rest of expert discovery, including but not limited to bellwether expert discovery, pharmaceutical sales and/or marketing experts and even regulatory affairs/FDA experts, would occur after this bifurcated general causation expert discovery period.

initially noted, is a concept that has already seemingly been rejected; and (d) will result in the nullification of the parties' prior agreements to stagger the non-AbbVie Defendant discovery behind that of the AbbVie Defendants. In short, any modified bifurcation of general causation will likely result in this MDL becoming entirely unruly and unmanageable for both the parties and the Court. Finally, the AbbVie Defendants' revised case management plan is also insufficient in that it attempts to provide a discovery date cut-off, which as discussed in further detail below, is entirely inappropriate under the facts here where potentially relevant discovery is continuously manufactured by Defendants, Plaintiffs and even scientific and/or medical healthcare professionals.

As such, the PSC respectfully submits that the Court should adopt its amended Uniform Case Management Plan [Dkt. No. 450-1], and decline to adopt the re-tooled bifurcated version of the plan submitted by the AbbVie Defendants in its entirety.

II. The AbbVie Defendants' Modified Bifurcation of General Causation Greatly Prejudices the Plaintiffs and Will Result in Complete Discovery Chaos

As noted above, in their amended Uniform Case Management Plan, the AbbVie Defendants again propose that this case should be bifurcated. This proposal, of conducting general causation expert discovery first is not only inefficient, but also greatly prejudices the Plaintiffs in the following ways.

First, as was made clear at the November 5, 2014 case management conference, to the extent that the Court were to adopt the AbbVie Defendants' revised case management plan with respect to bifurcation, and have general causation discovery, including *Daubert* hearings and/or summary motions prior to bellwether discovery, all non-AbbVie Defendants will want to have a role in this process, where as previously the Non-AbbVie Defendants agreed to have staggered discovery. As a result, counsel for the non-AbbVie Defendants will not be agreeable to a discovery

schedule that staggers behind that of the AbbVie Defendants as they will be bound by a global decision on general causation at the end of that discovery period. In short, the non-AbbVie Defendants will want to participate in a discovery process that culminates in a ruling that will be enforced against them.²

In oral argument, counsel for the AbbVie Defendants questioned why simultaneous discovery on all six (6) Defendants would be difficult for Plaintiffs when one reason for a large PSC was so that it could be divided into separate teams to handle discovery for each Defendant. While it is true that a large PSC is required to handle complex litigation against six (6) separate Defendants in multi-district litigation, it is not a reason that all such discovery should proceed against all six (6) Defendants at the exact same time. Regardless of the size of the PSC, the better approach is to stagger discovery with respect to each Defendant so that the PSC can build the foundation of their case with respect to each Defendant one building block at a time. This is the most efficient approach for both the parties and the Court as both will be guided by the process as well as direction and/or rulings by the Court with respect to discovery disputes and the like, rather than arguing these disputes six (6) times over.

Moreover, conducting simultaneous discovery on all six (6) testosterone manufacturers also negatively impacts the Plaintiffs because it will require that the PSC receive, review and digest millions of pages of documents from six (6) different testosterone replacement manufacturers all

² As the Court is now aware, it was the intention of all the parties, including the AbbVie Defendants, that discovery pertaining to the non-AbbVie Defendants would be staggered, and would commence at some point after the AbbVie Defendants. Moreover, because the parties were in agreement that the non-AbbVie discovery would commence after the AbbVie discovery, the Plaintiffs have not yet even served 30(b)(6) notices on any of the non-AbbVie Defendants with one single exception. This agreement has been in place since least as the date of the entry of Case Management Order No. ("CMO") 7, when the PSC agreed to serve initial discovery only on the AbbVie Defendants. However, now, three (3) months later, in order to have their general causation discovery plan adopted by the Court, the AbbVie Defendants are now willing to do anything so that general causation discovery is decided in the first instance.

at the same time and on the exact same schedule, and all well in advance of conducting *any* depositions of corporate personnel from six (6) different testosterone replacement manufacturers.

For illustrative purposes, and by way of comparison, in two recent MDLs in Illinois, in the In re Pradaxa (Dabigatran Etexilate) Prods. Liab. Litig., MDL No. 2385, the Defendants produced approximately 80 million pages of documents for a drug that had only been on the market since 2010, and moreover, the timeframe within which to complete fact discovery was over a year. Similarly, in the In re Yasmin and YAZ (Drospirenone) Marketing, Sales Practices and Prods. Liab. Litig., MDL No. 2100, the Defendants produced approximately 90 million pages of documents for an oral contraceptive that had been on the market since 2001. The AbbVie Defendants' testosterone replacement product, Androgel, has been on the market longer than either of the aforementioned drugs, and thus one would expect significantly more documents for just this one Defendant.

However, under the AbbVie Defendants' revised proposal, Plaintiffs' would receive document productions of this magnitude from all six (6) testosterone replacement manufacturers on the same schedule, and have to complete a review and digest the contents of those documents while taking depositions.³ Finally, as noted below, this discovery would all need to take place within approximately nine (9) months, and as the Court is well-aware, the AbbVie Defendants have been less than forthcoming in producing discovery, and frankly, the PSC does not expect that this will change. As such, requiring the PSC to conduct and complete discovery against all six (6) Defendants in nine (9) months is likely not possible.

³ It is critical to point out that in reviewing these millions of pages of documents, Plaintiffs must digest them, which includes learning the science contained therein, and often times, request supplemental productions in light of their document review, and finally, consult with their experts about the reviewed documents. To add to this overwhelming task, Plaintiffs must also prepare to take complicated depositions of science and medically-trained defense witnesses, and perhaps then seek supplemental witnesses, in addition to the serving of expert reports all by September 1, 2015, this becomes nearly impossible. If five (5) additional defendants are added to that undertaking, the task becomes even more unlikely to be possible.

As briefly noted above, all of this document review as well as all of these depositions would have to occur simultaneously, and pursuant to the AbbVie Defendants' revised case management plan, within a nine (9) month timeframe.⁴ This likely would result in an unmanageable and chaotic MDL, and will greatly prejudice the Plaintiffs.

Inevitably, and as noted above, the Court would be faced with multiple discovery disputes between Plaintiffs and one or more (if not all six) Defendants, including scope and/or objections to deposition notices, privilege designations and/or other discovery disputes all at the same time. These disputes will require the Court to schedule multiple and duplicative hearings where similar discovery issues are briefed and argued multiple times. This will completely bog down the discovery process, and ultimately, likely halt this MDL from being able to move forward. By staging the discovery with the AbbVie Defendants' going first, the parties will be able to meet and confer, brief and argue any discovery disputes one time, and then use the outcome of those disputes as needed and/or as relevant to guide the discovery against the Defendants that follow. The result will be an efficient and streamlined discovery process rather than a mass uncontrolled free for all.

Further, and as set forth in Plaintiffs' initial underlying brief (Dkt. No. 428), such a draconian discovery plan as the AbbVie Defendants have proposed will also likely send cases to state court as most Plaintiffs' lawyers would not willingly consent to subjecting their respective clients to such distinct prejudice.

In short, requiring the Plaintiffs to undertake discovery against all six (6) testosterone manufacturers at the same will jeopardize the Plaintiffs' ability to appropriately and adequately discover their case. Finally, the scope of discovery and the timeframe within which the Plaintiffs

⁴ Plaintiffs have already agreed not to commence depositions until no earlier than January 2015 against all Defendants, and as such, under the AbbVie Defendants' plan, the Plaintiffs would have nine (9) months to completely discover their entire case both with respect to written discovery as well as depositions against six (6) different testosterone manufacturers concurrently.

have to conduct it, should not be limited to the detriment of Plaintiffs, when it is the AbbVie Defendants who have already significantly delayed the production of documents and witnesses for nearly the last three months, including but not limited to responses to Plaintiffs' documents requests,⁵ responses to Plaintiffs' interrogatories, production of the IND/NDA, and production of witnesses in response to 30(b)(6) deposition notices.

Moreover, the AbbVie Defendants' revised case management further prejudices Plaintiffs, because the schedule contemplates a deadline for general causation expert reports that is one day after the depositions of fact witnesses are scheduled to be completed. Plaintiffs' expert witnesses will rely on the deposition testimony of the Defendants' fact witnesses, under the AbbVie Defendants' revised case management plan, fact witness deposition theoretically could continue up until the day before the Plaintiffs' expert reports are due. This is clearly not realistic as Plaintiffs' experts will need to be in possession of all materials and/or deposition transcripts upon which they will rely in forming their opinions more than one day in advance of the deadline to submit their reports.

For each and every one of the above reasons, the AbbVie Defendants' revised case management plan prejudices the Plaintiffs and will turn this MDL into a potential disaster for all parties involved.

III. There is No Basis to Bifurcate General Causation Because General Causation is Not In Question

As discussed at length in the PSC's initial brief in support of their case management plan (Dkt. No. 428), there is no valid reason to bifurcate general causation discovery in this case. To

⁵ Notably, the Plaintiffs are still not in possession of even the easiest of documents to produce, including the IND/NDA and/or the production in *United States ex rel. King v. Solvay S.A., et al.*, United States District Court, Southern District of Texas, case no. H-06-2662.

recap briefly, in the package insert that accompanies testosterone replacement products, there is a specific warning relating to the risk of venous thromboembolism.

The heightened warning was added in June of this year, at which time the FDA stated as follows:

The U.S. Food and Drug Administration (FDA) is requiring manufacturers to include a general warning in the drug labeling of all approved testosterone products about the risk of blood clots in the veins. Blood clots in the veins, also known as venous thromboembolism (VTE), include deep vein thrombosis (DVT) and pulmonary embolism (PE).

While Plaintiffs submit that the warnings relating to blood clots are, and always have been, insufficient, Defendants' warnings regarding blood clot risk associated with testosterone therapy is significant evidence of biological plausibility and general causation, and the PSC believes largely establishes general causation for this category of cases.

Similarly, with respect to cardiovascular events, as the Court is now aware, on September 17, 2014, an FDA Advisory Committee panel heard testimony from industry representatives, independent medical experts, and men gravely injured by testosterone replacement therapy concerning the risk of cardiac events associated with testosterone replacement therapy.⁶ The result was nearly unanimous: the panel recommended overwhelmingly that the FDA compel testosterone replacement therapy manufacturers (these same Defendants) to conduct more extensive research on the correlation between testosterone replacement therapy and cardiac events.

⁶ This FDA panel, comprised of experts in various disciplines were invited by the FDA to consider issues related to the use of testosterone therapy, and made recommendations to the FDA concerning the appropriateness of the labeling of testosterone products as well as the need for manufacturers to conduct further studies regarding the association between testosterone products and cardiovascular risk. While the findings of the panel are not binding on the parties in this litigation, nor is the FDA required to follow the panel's recommendations, the initial message from the panel of experts was clear that there is the potential for risk associated with testosterone products, and there is no evidence of benefit of these drugs for men suffering from age-related hypogonadism, a population for which these drugs are not approved.

The above makes clear that there is sufficient epidemiological evidence related to the association between testosterone replacement products and the aforementioned injuries that make any sort of bifurcation of general causation entirely inappropriate in this case. For this reason as well, the PSC respectfully submits that the Court should decline to adopt any form of bifurcated general causation.⁷

IV. The PSC Opposes the AbbVie Defendants' Request for Modified Bifurcation of General Causation (again)

A. This Court Seemingly Already Rejected Bifurcated General Causation

As discussed above, in their revised case management plan, the AbbVie Defendants once again propose general causation in advance of the case-specific case. More specifically, the AbbVie Defendants propose that general causation discovery should occur between November 14, 2015 and August 31, 2015, with the expert portion occurring from September 1, 2015 to February 15, 2016. This general causation discovery period would include *Daubert* and Summary Judgment motions pertaining to general causation only. After the parties filed any *Daubert* and/or Summary Judgment motions, then in January 2016, the parties could commence bellwether discovery. For the reasons set forth below, as well as the reasons set forth in our initial brief (Dkt. No. 428) and argued at the October 24, 2014 Status Conference with Your Honor, the PSC (still) vehemently opposes bifurcation of general causation discovery, and respectfully submits that the Court should decline to adopt this aspect of the AbbVie Defendants' revised case management plan in its entirety.

First, and importantly, the concept of bifurcated general causation is a concept that the AbbVie Defendants have already proposed, and that this Court seemingly already rejected. At

⁷ Indeed, when this was argued the first time, Your Honor appeared to agree that such a protocol may not be appropriate. *See* fn. 9, *infra*.

the hearing on November 4, 2014, the AbbVie Defendants failed to proffer any new and/or additional valid bases for why any form of bifurcation of general causation is appropriate in this case, and as such, there continues to be no valid reasons for the Court to change its course with respect to its apparent rejection of bifurcation of general causation. In fact, given the agreement between of the PSC and the non-AbbVie Defendants to proceed with a staggered discovery track, per the PSC proposal, the opposite is true.

In sum, the Court previously seemed to reject the AbbVie Defendants' general causation first concept, and as such, this request should be construed as nothing other than an attempt to shortcut the procedures that would otherwise be in place for a motion for reconsideration and/or re-argument. The PSC does not appreciate this sand-bag attempt by the AbbVie Defendants who never raised this proposal during either of the two meet and confers following the October 24, 2014 hearing, and which the Court appeared to catch wind of and noted in its Minute Order [Dkt No. 451], which leads to only two possible logical conclusions, either: (1) the AbbVie Defendants were entirely abusing the meet and confer process and intended to lay and wait until the time of their filing; or (2) this concept was concocted on the eve of the filing deadline and thus never shared with the PSC. Neither scenario is appropriate.

Further, as noted above, at the October 24, 2014 case management conference, this Court made clear that the parties were to utilize the PSC's general case management form stating "[y]ou're going to be working off the form that the plaintiffs started off with and just seeing if you can tweak or modify the bellwether selection process." *See* October 24, 2014 Hearing Tr. at p. 54:21-23. This statement was seemingly also affirmed in the Minute Entry following the conference in which the Court stated "[it]...has made suggestions regarding possible modifications to plaintiffs [proposed uniform case management plan]; proposed draft order, regarding the

selection of bellwether cases." (Dkt No. 441). The plain and unambiguous words contained within the Court's Minute Entry made it clear that the Court's intention was that the modifications that were to be made to the Plaintiffs' proposed case management plan should be limited to timing/deadlines related to the bellwether process, and not include this modified version of a bifurcation of general causation discovery.⁸ Moreover, the Court also appeared to reject this general causation approach previously.⁹

Similarly, and equally significant, at the October 24, 2014, the Court made clear that bifurcation of general causation was extremely inefficient unless the AbbVie Defendants were to win all issues related to general causation across the board stating specifically:

But, you know, the problem on the other side is that if you end up not prevailing - if the defense ends up not prevailing on the summary judgment, all of a sudden this looks like an incredibly inefficient way of doing things, because we have gone two years down the road, or whatever it is. *See* October 24, 2014 Hearing Tr. at pp.43:24-44:5

⁸ While counsel for the AbbVie Defendants did state towards the end of the conference, "[o]ne thing I think we would like to talk about with plaintiffs is alternate ways to structure the timing of a *Daubert* motion on issues of general causation," and while the Court indicated that it would allow this discussion, this issue was never actually discussed with the PSC. *See* October 24, 2014 Hearing Tr. at pp.55:24-56:5. Indeed, the AbbVie Defendants sprung this concept on the PSC for the first time in their proposed plan knowing that the Court had expressly did not intend to permit a reply brief. *See* October 24, 2014 Hearing Tr. at p. 56: 17-19 (indicating that there was "not going to be any reply briefs or anything like that.").

⁹ In fact, it is worth noting that at the October 24, 2014 Hearing, Your Honor even stated:

I will tell you, honestly, part of my concern with this motion -- and I don't say this critically --it's a little bit of a mini summary judgment motion. It kind of is. I mean, you're asking me to make sort of a preliminary indication, yes, this is kind of a weak case and so I should do it this way. I have some sort of visceral discomfort about that just from life experience as a judge. *See* October 24, 2014 Hearing Tr. at p. 43: 15-22.

Respectfully, it is not clear what part of the AbbVie Defendants' modified bifurcation of general causation would alleviate this "discomfort," as the plan still turns tested and accepted discovery protocols on their head. The AbbVie Defendants' protocol would force the Plaintiffs to discover their case in the way that the Defendants choose, which again, is contrary to established procedure and the basic tenants of the Federal Rules of Civil Procedure. As discussed at length in Plaintiffs' initial underlying brief (Dkt. No. 428), and as set forth below in Section III, *supra*, there is simply no valid basis for doing this, and the AbbVie Defendants have still failed to offer any.

Nothing has changed with respect to the AbbVie Defendants' proposal for bifurcation of general causation discovery, however notwithstanding this fact, the AbbVie Defendants have still sought to rehash each and every one of the Court's recommendations related to the parties' respective case management plans and attempt to re-present them to the Court. Again, there simply is no basis to revisit these issues as the basis and/or rationale for rejecting any form of bifurcation of general causation first is equally strong regardless of whether one is talking about complete bifurcation of general causation, or rather some modified version.

B. General Causation Should Be Done in the Context of a Specific Case

Moreover, as was discussed at length in PSC's initial brief (Dkt. No. 428), it is critical that the general causation inquiry, including *Daubert* motions and/or hearings be undertaken in the context of a specific case or cases. There are countless efficiencies gained from conducting general causation in the context of a specific case, including but not limited to the fact that many of the experts that will opine on general causation will likewise opine as to specific causation.

More specifically, and by way of example only, experts such as hematologists and cardiologists, who will likely opine generally as to the fact that testosterone replacement drugs can cause clotting injuries and/or cardiovascular injuries, respectively, will also likely be the same individuals who would provide specific causation for the bellwether cases alleging the aforementioned injuries. If general and specific causation are done in two separate phases, then these busy medical professionals will have to provide two reports at separate times in the process and be deposed twice, which significantly increases the expense for the Plaintiffs, who will be required to produce these experts twice, and pay all expenses associated with their travel, time and deposition preparation on two separate occasions. It also increases the costs for the Defendants by requiring two depositions (including the travel expenses and the time in preparing and taking the

two depositions). It goes without saying that this would be extremely inefficient and not cost effective.

In the AbbVie Defendants' brief in support of their revised case management plan (Dkt. No. 449), the AbbVie Defendants contend that "an early decision on general causation promises efficiencies and savings to all parties no matter what the Court decides." *See* Brief at p. 1. However, as discussed above, and as the PSC and the Court have *already* pointed out at the October 24, 2014 hearing, the "efficiencies" that the AbbVie Defendants contend that this modified bifurcation of general causation will have, only actually occur if the AbbVie Defendants are successful in winning their *Daubert* motions, which is a proposition that the PSC strongly contests.¹⁰ Further, as noted in footnote one above, there are many other expert witnesses and disciplines that will still require work up.

Conversely, under the PSC's amended Uniform Case Management Plan, not only would a ruling on general causation discovery be complete at the time of *Daubert* hearings, but so too would all bellwether expert discovery. Moreover, and as noted above, because many of the experts opining on general causation will also opine as to specific causation, it is incredibly inefficient to force these people to be produced twice. Concurrent case specific and general causation expert discovery produces the most effective and efficient case management protocol, and as such, the Court should decline to bifurcate general causation discovery in any way, including this modified version.

Finally, the reality is that bellwether discovery is not that extensive, and thus conducting it concurrently with the other case discovery (albeit slightly delayed as the Court requested at the

¹⁰ As explained more fully in Section III, *supra*, the medical literature is replete with epidemiological evidence identifying a clear association between thromboembolic and cardiovascular events and use of testosterone replacement products.

October 24, 2014 hearing) is not as daunting as the AbbVie Defendants would have the Court believe. Indeed, proceeding with this method and plan is how the vast and overwhelming majority of pharmaceutical MDLs proceed. In the PSC's amended case management plan, it proposes that the parties nominate 32 bellwether cases.¹¹ Moreover, the number of depositions per case is limited to 4 depositions per side, and many of these depositions likely will not require full days. Finally, if the AbbVie Defendants do not wish to take four (4) depositions in every case, they certainly are not required to, and thus can further limit the extent of bellwether discovery by opting not to conduct all four (4) depositions to which they would be entitled under the Plaintiffs' proposed case management plan.

Indeed, it is for all of the above reasons that the Amended Uniform Case Management Plan that the PSC proposes is wholly consistent with virtually all pharmaceutical MDLs, and respectfully the PSC submits, the Court should decline to adopt the novel, unproven and potentially disastrous proposal that the AbbVie Defendants are still clinging on to.

V. The AbbVie Defendants' Eleventh Hour Proposal Invalidates the Defendants' and the PSC's Agreement to Stagger Discovery

Adoption of the AbbVie Defendants' revised case management plan would also result in the invalidation of the parties' agreements to stagger discovery. As the Court is aware, prior to the AbbVie Defendants' last minute proposal modifying bifurcation of general causation discovery, both the AbbVie Defendants and the non-AbbVie Defendants were in agreement that discovery pertaining to the non-AbbVie Defendants would commence after that of the AbbVie Defendants and proceed on a slightly staggered schedule. This "agreement" has been contemplated since at least the entry of CMO No. 7, wherein it is clearly articulated that as of the date of the entry of that

¹¹ Notably, in its brief in support of its amended case management plan, the PSC also noted that it would be agreeable to decreasing this number to 24 should the Court deem that number more appropriate.

Order, discovery demands had only been served on some Defendants. *See* CMO 7 at ¶3B. While initially a tacit agreement, this was an agreement to which the AbbVie Defendants were both privy to and in accord with. Since CMO 7, the agreement to proceed in this fashion has been memorialized both in the Plaintiffs' two briefs in support of their case management plans (Dkt. Nos. 428 and 445) as well as in the Exhibit As that were attached thereto.

However, now, when faced with the proposition that their general causation first proposal may not be adopted by the Court, the AbbVie Defendants want to renege on these agreements and force the non-AbbVie Defendants to do the same. As noted above, and was made clear by Mr. Solow at the November 4, 2014 case management conference, who unofficially spoke on behalf of all non-AbbVie Defendants, to the extent that Your Honor now entertains and/or revisits the idea of bifurcation of general causation, then the non-AbbVie Defendants will advocate for full blown fact discovery to be conducted on their clients concurrently with that of the AbbVie Defendants. *See* November 4, 2014 Hearing Tr. at p. 15: 18-23 (stating "in the event your Honor now decides...a threshold universal general causation proceeding, is the best course of action, we have told the PSC and AbbVie our view is we're not missing the boat on that."). While the PSC can appreciate the non-AbbVie Defendants' position in this regard, it is the AbbVie Defendants' eleventh hour proposal that is forcing all of these prior agreements to be undone, and thereby causing the potential for total upheaval in the discovery process.

VI. A Discovery Cut-Off Date is Not Appropriate Where a Drug Is Still on the Market

Finally, the provision of the AbbVie Defendants' case management protocol, which identifies a deadline for the completion of all discovery is improper. Testosterone replacement products are still on the market, and thus potentially relevant documents continue to be created likely on a daily basis. Moreover, the linchpin of litigation is that it is a search for truth, and if by

way of example, that truth were to become evident, in part, in the form of FDA action that occurred after a designated discovery deadline set forth in a case management order, the Plaintiffs should not be foreclosed from discovery related to any such FDA action. Such discovery would clearly be both relevant and critical to Plaintiffs' case. As counsel aptly articulated at yesterday's hearing, this is not a case where there is a "closed universe" of discovery as in a medical malpractice of car accident case, in this case, the discovery is ongoing. *See* November 4, 2014 Hearing Tr. at p.17:10-12. While it is true that the overwhelming and vast majority of the discovery that the Plaintiffs will conduct on the Defendants should be complete prior to the expert report deadline, there will still be ongoing discovery in all areas, including but not limited to science, adverse events, medicine and/or liability.¹²

As such, the AbbVie Defendants should not be entitled to a deadline after which they are no longer required to comply with discovery obligations. Simply put, there cannot and should not be a deadline for the completion of discovery while these products continue to be on the market.

VI. Conclusion

In light of the foregoing, the PSC respectfully requests the Court adopt its proposed Amended Uniform Case Management Plan, and reject the AbbVie Defendants' revised case management plan in its entirety.

Respectfully Submitted,

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¹² The science pertaining to these cases continues to develop, scientific and medical articles continue to be written, and testosterone replacement drugs continue to be marketed by sales representatives and commercials. As such, what these Defendants knew and when they knew of information, and how they react to such information remains critical. As new information develops, these questions and discovery related thereto should be permitted.

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CERTIFICATE OF SERVICE

I, Brian J. Perkins, hereby certify that on November 5, 2014, I electronically transmitted a true and exact copy of the foregoing document, to the Clerk of the Court using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing to all attorneys of record who are ECF registrants.

/s/ Brian J. Perkins